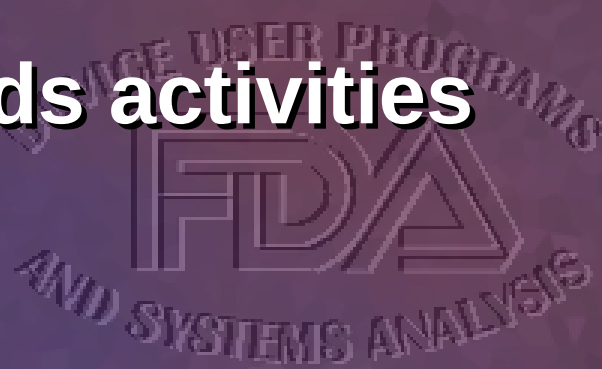
IEC Develops Standard for Medical Device Human Factors Design

Ensuring a safe device-user interface

Overview

- What is the magnitude of the use error problem?
- Examples of device use error problems
- The role of human factors engineering
- IEC SC62A HFE standards activities

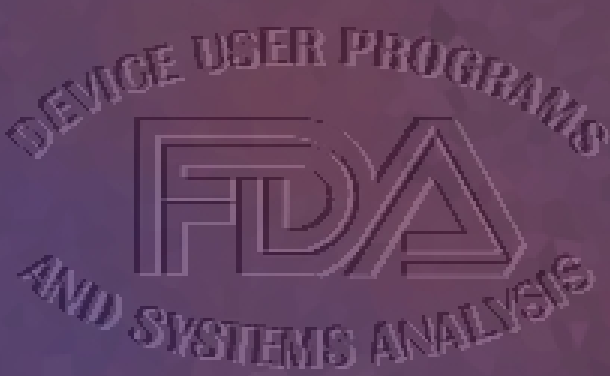


Basic Assumptions

- A flawed device-user interface can induce error
- Warnings and instructions in the operating manual can’t fix a flawed device-user interface

FDA Medical Device Incident Reports:

- 80,000 reports per year
- More than 1/3 involve use error



To Err is Human: Building a Safer Health System

Institute of Medicine,
National Academy of Sciences

November 1999

Medical Errors in U.S. each Year Result In:

- Up to 98,000 deaths
- $29 Billion added cost

Anesthesia Patient Safety:
20 fold improvement in 10 years

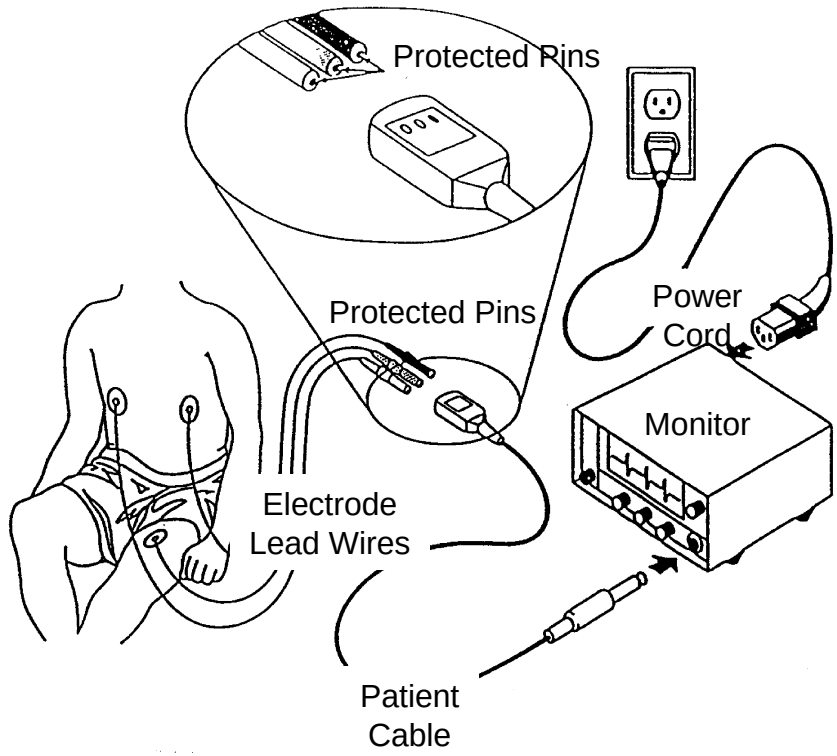
- Technological advances (pulse oximeter)
- Standardization of equipment
- Changes in training

ANSI standard for gas machines

- 70% of the requirements dealt with use error

SAFE

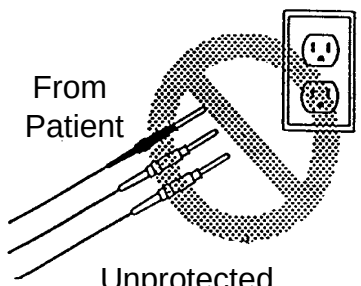
Lead Wires with Protected Pins and Correct Connections

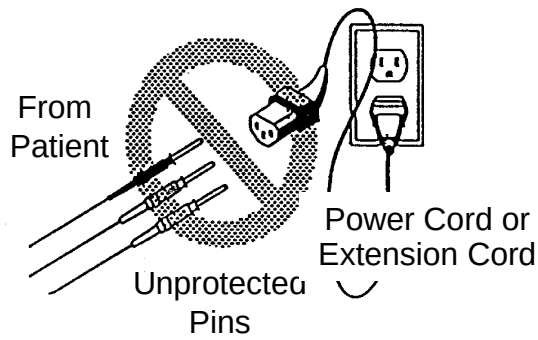


Use only lead wires that have protected pins. Protected pins can not accidentally be plugged into power cords or electrical outlets.

UNSAFE

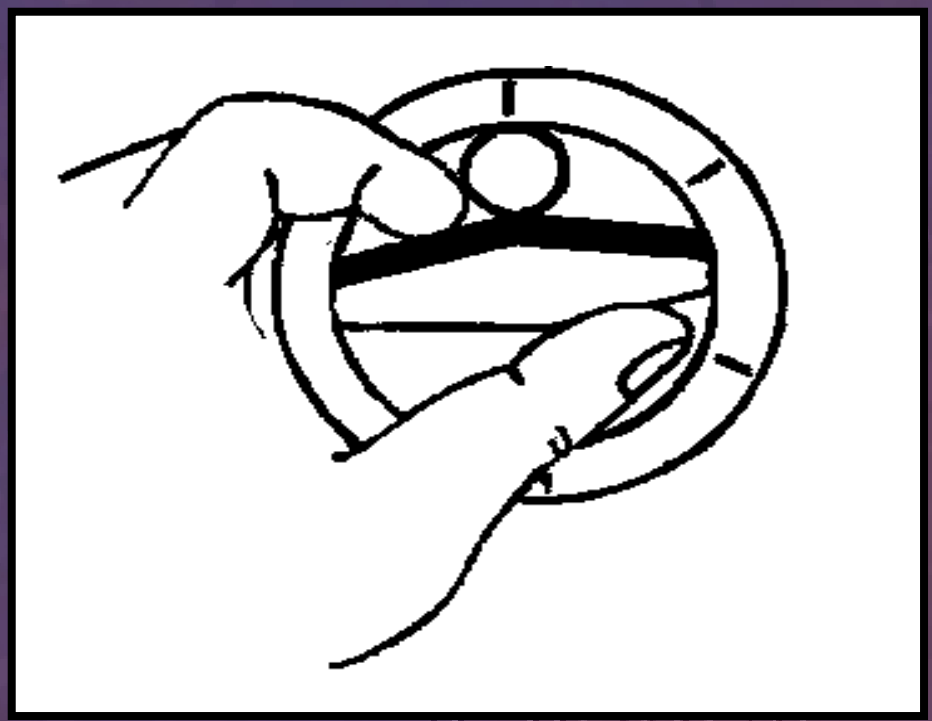
Lead Wires with Unprotected Pins and Incorrect Connections





Flow Knob with Accompanying Instructions

Turn the flow knob to the proper flow number. Be sure the dial pointer and is not between numbers.

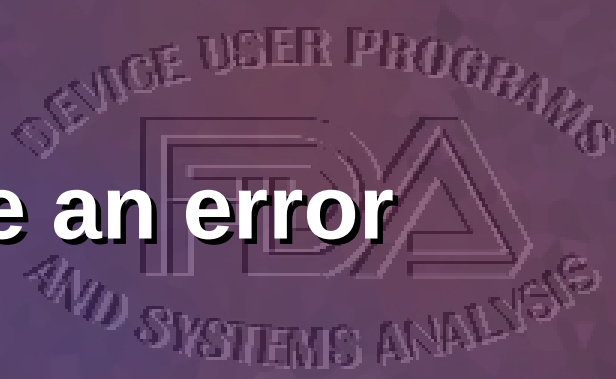


Desirable Design Characteristics

- Operations - don’t exceed user capabilities
- Information - Sufficient, legible and intelligible
- Procedures - logical and intuitive
- Operations - consistent with conventions
- Dangerous error - designed out
- Conditions of use - considered and addressed

Key safety design concepts

- make things visible
- simplify the operation
- avoid reliance on memory
- avoid reliance on vigilance
- use natural mappings
- use forcing functions
- make it easy to reverse an error



Important Statutory and Regulatory Changes

- **Quality Systems Regulation/ CGMP - Design Controls (1996)**

(Essentially same as ISO 9001)

Design Controls

- **Regulatory Language:**
  - **"… design requirements … intended use … needs of the user and patient."**
  - **"… testing production units under actual or simulated use conditions."**
  - **"… conduct risk analysis."**

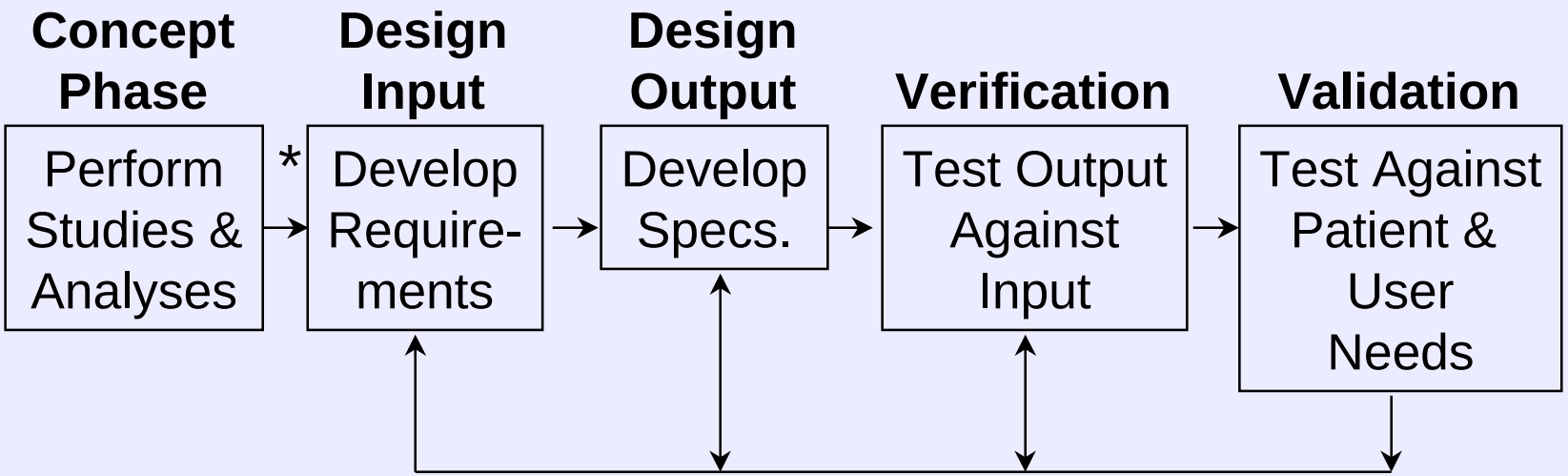
Design Controls

- **Preamble Language:**
  - **"… conduct appropriate human factors studies, analyses, and tests …"**
  - **"… human interface includes both the hardware and software characteristics…"**

Design Controls - Human Factors Engineering (HFE) Process

- HFE applied from concept stage to final design
- Early Involvement of typical users is critical
- The process is iterative

Human Factors Engineering Process



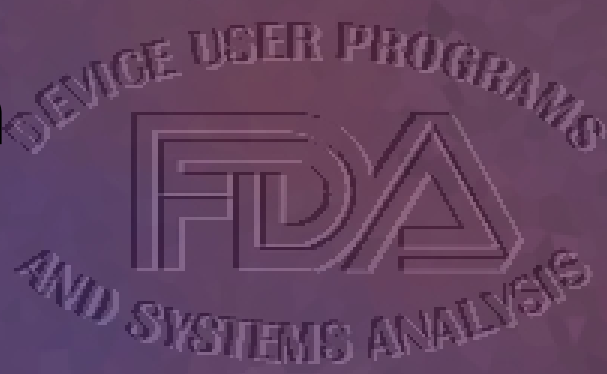
HF Elements

Literature	Safety	Drawings	Analyses	Production Units
Complaints	Environment	Mockups	Expert Evaluation	Full Usability Test
Observation	Users Performance	Computer Prototypes	Rapid Prototyping	Risk Assessment
Interviews				

*Design and Development Planning Important Here

Human Factors Engineering - Summary of Methodology

- Study the user population and use conditions
- Analyze function, tasks, and hazards
- Incorporate findings in requirements



Human Factors Engineering - Summary of Methodology

- Test and analyze prototypes against requirements
- Test production models in simulated environment
- Conduct a risk assessment

IEC SC62A WG5

Symbols and Ergonomics

IEC 60601-1-6:

Collateral Standard: Usability, analysis, test and validation of human factors compatibility.

IEC 60601-1-6

- General requirements: USE ERRORS
  - USE ERRORS and their consequences shall be limited to an acceptable SAFETY level to satisfy RISK MANAGEMENT. This shall be accomplished by applying a documented HUMAN FACTORS ENGINEERING PROCESS (e.g., Annex 8)

IEC 60601-1-6

- **HUMAN FACTORS ENGINEERING PROCESS shall include a risk analysis. The risk analysis shall include a description and assessment of the OPERATOR characteristics and requirements, task requirements and potential USE ERRORS.**

IEC 60601-1-6

- General requirements for tests
- USABILITY TESTING shall validate adequate USABILITY for the INTENDED PURPOSE of the EQUIPMENT.

Other International Standards

- ISO 14971-1, Risk Management Process
  - will require assessment of potential use error
- IEC 60601-1, 3rd edition, Electromedical Equipment Standard
  - will include requirements to protect against use error

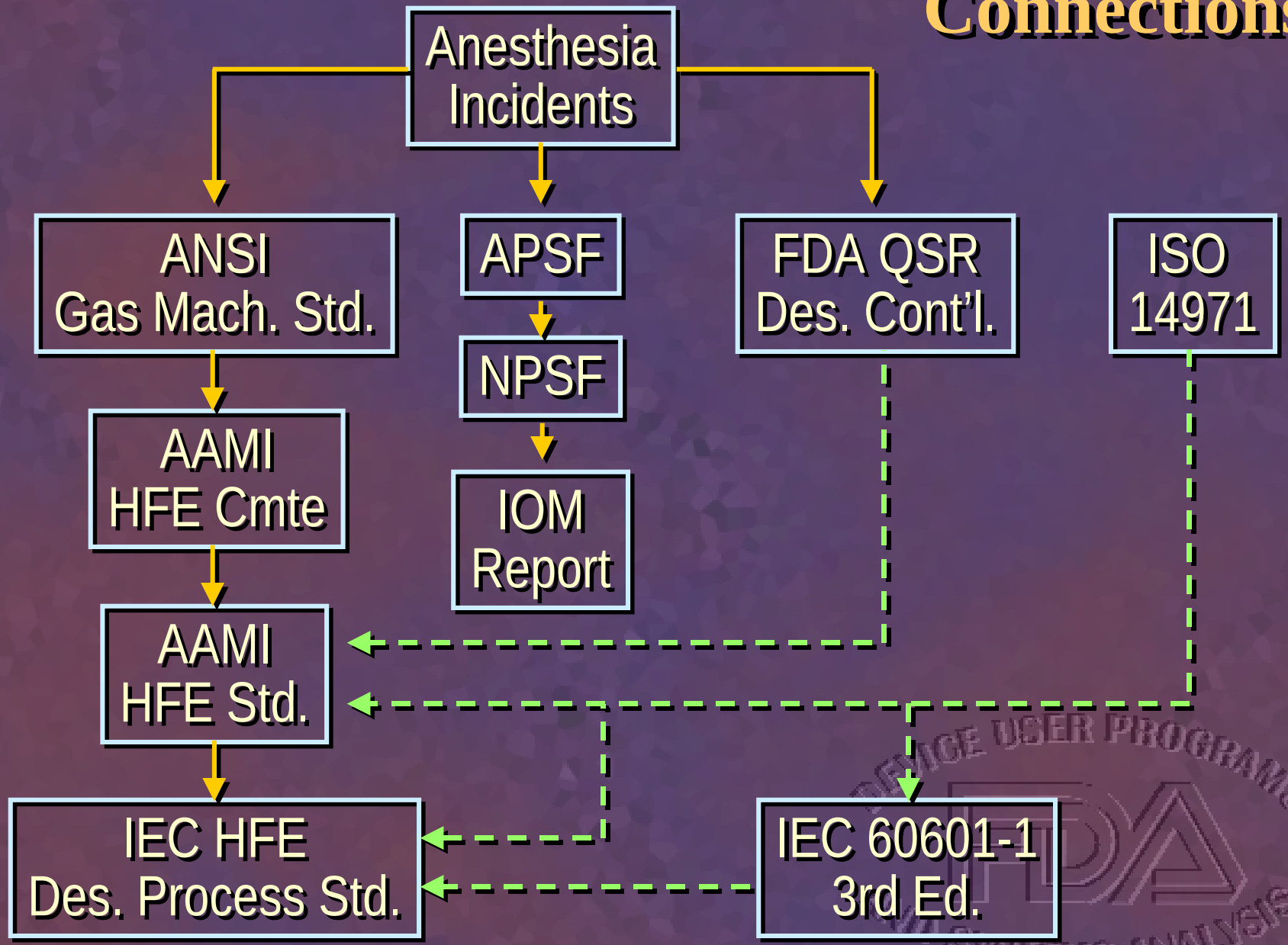
U.S. & International Standards

- ISO 14971-1, Risk Management Process
  - Describe intended use including any reasonably foreseeable misuse.
  - Annex A and D - questions to ask and examples of hazards

ANNEX 8: AAMI HE48-1

Human factors design process for medical devices –
Part 1: Human factors engineering guidelines and preferred practices for the design of medical devices

Connections



The Future

- **IEC 60601-1-6 2nd edition**

  3 years after publication of the 1st edition - add AAMI Part 2

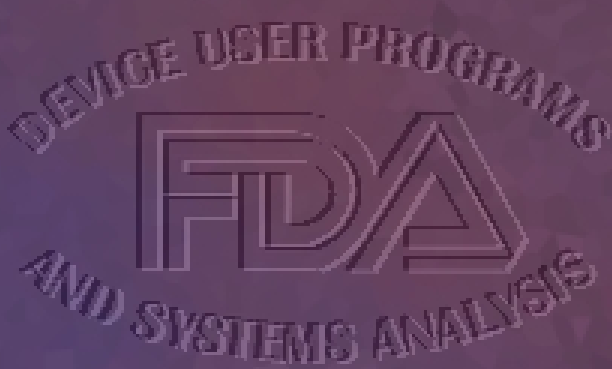
- **Joint IEC/ISO 60601-1-6**

  Begin by 2002

FDA Web Site

- http://www.fda.gov/cdrh/humanfactors.html

  fda.gov/cdrh/usererror.html



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